Update on the Implementation of the

Genetic Information Nondiscrimination Act

Amy Turner, J.D. and Russ Weinheimer, J.D.

MS. TURNER: Thank you very much. It's nice to be here.

For years, I've had the pleasure of participating as the Labor Department's alternate ex-officio member to some of these meetings. I feel like I've listened, for years, to people asking people who came from Congress, why can't we get this GINA legislation passed, why can't we get this GINA legislation passed.

I had the luxury of not being in the hot seat and thought, not my turn yet; I'll just listen and hear what these congressional staffers have to say. Then GINA was passed in May 2008, and I heard that some of you were asking, where are those regs, where are those regs. I skipped those meetings, not because I was avoiding answering your questions but because we were actively working on writing those regs.

So I am happy to announce that, yesterday, those regs were published. I don't know if they are in your materials, but I'll give you a site in case.

DR. TEUTSCH: They should be in your folders.

MS. TURNER: Excellent, fabulous. So you'll have them. So you can enjoy them tonight with a glass of chablis in your wonderful suite upstairs at the Park Hyatt. They are fine reading, those regulations.

I thought I would start, just in case you're wondering, geez, why are there so many government bureaucrats sitting up there, I might just take a few minutes to explain why there are so many government bureaucrats sitting up here.

GINA is a far-reaching law; it does a lot. Sections 101 through 104 deal with nondiscrimination in health coverage. Russ from the IRS, myself from Labor, and Jim Mayhew from CMS, all worked together, and also collaboratively with the states, to administer the health coverage nondiscrimination provisions.

GINA Section 105 deals with privacy and that is HHS's Office of Civil Rights, that is why Robinsue and Christina are here. Then Title II deals with the employment discrimination provisions which is the EEOC.

So if you're wondering why there are so many of us up here, it's because GINA does a lot, and we're all

here to administer it and enforce it.

So what I'm going to focus on, with Russ and Jim, are the health coverage nondiscrimination provisions. I'm going to subdivide those, as well, because my brain works in outline format. There are group market provisions, individual market provisions, and Medicare supplementary policy provisions.

The group market provisions are administered jointly by Labor, IRS, and CMS. If you're wondering, again, why so many government bureaucrats, I think not only does that inform the interpretive process but it's to make sure that GINA is enforceable.

Those group market provisions, what that means is that is for individuals who get their health coverage through their employer. That is the group market. You're put into a group. So if I work for Russ's widget company, we're all in an employment-based group and we have group market coverage.

There are lots of different employers out there. There are private employers, there are state and local government employers. The employer is responsible for making sure that his health coverage complies, but the

employer may choose to do what is called a self-insuring the plan, particularly if he is big.

I don't want to pick on a particular employer, but let's say it's IBM or something like that. They may choose to self-insure, but your smaller employers may tend to go to an insurance company, Aetna, Cigna, something like that, and buy an insurance policy. Those insurance companies are also responsible for complying with GINA.

So to make sure that the insurers and the employers, whether they are private employers, or state and local government employers, or church employers, to make sure that they are all complying with the law, and that the government can enforce against all those different types of entities, and that, essentially, individuals can also enforce on behalf of themselves, that they have private rights of action, what GINA does is it amends all these different laws.

It sounds confusing. You probably don't have to worry about it too much. I can give an hour presentation on the GINA enforcement structure. If people have questions, I would be happy to answer them, but suffice it to say, I think the main message I wanted to send on that

is, it may seem complicated at first but that is to ensure that it works and that people get what they're entitled to. So that is the group market.

The individual market is a little bit more simple. That is administered solely by HHS and the states. Jim is going to talk about that. The individual market is an individual who just calls up BlueCross/BlueShield and says, I want a policy for me and my family unrelated to employment. The IRS and the Labor Department have nothing to do with those individual policies. We're only involved when people are getting their coverage through their employers. Then there are also Medicare supplemental policies, which Jim will mention.

So let's zone in and focus on the group market. Yes, I'll tell you one more quick joke I just thought of 30 seconds ago. Russ is here from the IRS. We've worked together for a long time. He is wonderful to work with. If you're afraid of talking to Russ because he is from the IRS, I can tell you that I've worked with him since 1996 and I have still yet to be audited.

So you don't have to feel like you have to give him a fake name or something. Feel free to share your

business card if you have some questions afterwards. I am not guaranteeing you won't be audited, but again, you don't have to feel like you have to use a fake name or something like that.

The group market provisions that Russ and I are going to focus on build on some protections that were already enacted as part of HIPAA, namely, if an individual has their health coverage through their employer, that health coverage cannot impose a pre-existing condition exclusion, based solely on the fact that an individual has certain genetic information.

Let's say that they have a mutation on their BRCA1 or BRCA2 gene. They are predisposed to getting breast cancer or ovarian cancer but it's not manifested yet, they don't actually have the disease.

Already in the group market for years, since HIPAA has been effective since 1997, an individual can't have a pre-existing condition exclusion imposed upon them, based solely on that genetic predisposition, in the absence of a diagnosis of a condition, an actual diagnosis of breast cancer or ovarian cancer, for example.

In addition, in the group market already under

HIPAA, the individuals within the group -- let's say we all work for Russ's widget company, so we're all one employment-based group -- we can't be charged different premiums and we can't be kept out of the plan, denied access to the plan, denied eligibility or [dis]continued eligibility, or have our benefits changed between us based on any health factor, including genetic information.

So let's say we all work for Russ's widget company. I can't be charged a higher premium than Russ or Christina, based on the fact that I'm the one with those bad genes. All similarly situated individuals within that employment-based group all pay the same premium, they get the same benefit package, they have the same rules for eligibility, regardless of any health factor, including their genetic information.

Then GINA comes in, and GINA adds some protections. I'm going to turn it over to Russ. There are three main protections in the group market and we are going to tag team and go back and forth a little bit, but I'll just mention that before we did these regulations that were published yesterday, we did do what we call an RFI, and that is because we're government people and we love

acronyms and we drop acronyms every time we can.

An RFI is a Request for Information. We published one in October of 2008 that was open for 60 days, I believe, where we got comments from the public, both consumer groups, the regulated community, which is essentially employers and insurance companies, a wide variety.

The Medical Information Bureau commented, a wide range of commenters gave us some information in response to specific questions we asked, and also generally on the statutory provisions, before we issued these regulations yesterday.

The regulations were actually made available to the public on October 1st. I know, at least on the Labor Department's website -- and I'm sure HHS has stuff, too -- but on the Labor Department's website, if you go to www.dol, as in Department of Labor, .gov/ebsa, as in Employee Benefits Security Administration, we also have, in addition to the regulations, some fact sheets and press releases and Q&As, and a little bit more plain-English summary of what is going on. So that may be helpful information, as well. That was made available October 1st.

And with that, I think I hit all the preliminaries. I'm going to turn it over to Russ to start.

MR. WEINHEIMER: Thanks, Amy. We're going to talk about the three substantive rules that GINA adds to what Amy already summarized with existing HIPAA, and has been the requirement for the past 12 or 13 years, that you can't discriminate in certain respects on the basis of genetic information. That was principally based on an individual.

The three rules that are added are, you now can no longer discriminate on the basis of the group rate. An insurance company can't charge a group a higher rate based on genetic information in the group. Insurance companies and plans cannot request or require an individual to undergo a genetic test, and insurance companies and plans cannot request, require, or purchase genetic information for underwriting purposes, or prior to or in connection with enrollment.

Now we're going to go into a little bit more detail about each of those rules, but I wanted to mention three other things that GINA does specifically that differs from the HIPAA framework that Jim, Amy, and I have been

operating under for the past 12 or 13 years.

There are these three agencies we have been dealing with, the Health Insurance Portability and Accountability Act, pre-existing condition rules, special enrollment rules, nondiscrimination requirements, the mental health parity rules, both the '96 ones and the ones that were enacted last year, the one on Women's Health and Cancer Rights Act, and the Newborns' and Mothers' Health Protection Act.

So we have shared on all these provisions. There are certain provisions that apply across all of those laws that we share, and there are three specific rules that are special for GINA that go beyond that general framework. I just thought this audience would be interested in those.

One is there is a general exception to all of these HIPAA requirements. I'm going to call them HIPAA, but it is HIPAA and related legislation, that if on the first day of a plan year, a plan has fewer than two participants who are current employees, they don't have to comply with any of those requirements.

Now, how many plans have fewer than two participants who are current employees? Well, for active

employees, there probably aren't going to be many plans. This is essentially a retiree plan exception, and that exception does not apply for GINA. For GINA, not only does it apply to plans of active employees, it also applies to plans covering only retired employees. So that is one difference.

The other two differences, I can mention, but I'm going to invite Amy and Jim to chime in because they are specific to their departments. The one for Amy's department is the Department of Labor.

Generally, the IRS has enforcement authority to impose an excise tax, and the excise tax is $100 per day per beneficiary for each day that the plan isn't complying with whatever one of those HIPAA laws is with respect to that beneficiary for each day. The Department of Labor has enforcement authority but it isn't any monetary one, like a $100 per day in general.

Do you want to go into what it is, or should I mention it?

MS. TURNER: I'll just mention generally, like Russ said, under the HIPAA enforcement framework, the Secretary of Labor can sue if there is a violation of

HIPAA, GINA, mental health parity, any of those laws, to bring a plan into compliance.

Also, under ERISA, which is the law that we administer, individuals have a private right of action, so they can sue, themselves, to get what they're entitled to, or the Secretary of Labor can.

We traditionally have not had civil monetary penalty authority against plans or issuers. GINA changes that. In addition to the excise tax authority that IRS has, the Secretary of Labor also is authorized to impose an excise tax against a plan, which is, again, an employment-based plan, kind of like, picking on GM, if GM is providing health coverage to its employees, there is a separate legal entity that is created called the GM Plan.

GM realizes -- its small employers don't necessarily realize it -- but there is a separate legal entity created called "The Plan". That plan is responsible for complying with ERISA as amended, including these GINA provisions. Now the Secretary of Labor can impose a civil monetary penalty against the plan administrator if GINA isn't being complied with.

Also, the Secretary of Labor can impose a civil

monetary penalty against insurance companies. We call them issuers. It's insurance companies and HMOs that sell policies to employers if they fail to comply.

So again, if you have the small widget company, and Russ says, I've got 20 employees; I just bought a policy from BlueCross; what did I know about GINA, we can go to BlueCross and say, but you guys knew better, and impose a civil monetary penalty against the insurance company or HMO for failure to comply with the GINA provisions in the group market.

MR. WEINHEIMER: It looks like we have a question.

DR. ASPINALL: Have there been any lawsuits filed, or any penalties levied since GINA has been enacted?

MR. WEINHEIMER: Well, we should tell you the effective date of GINA is plan years, beginning on or after May 21st, 2009. In general, that means for calendar-year plans, they're going to have to start complying January 1st, 2010.

So there may be some plans that, if they have a July 1st to June 30th date, are currently subject to GINA. It's just too early. I don't think that your agency has

taken any enforcement action yet.

MS. TURNER: Most plans are calendar-year plans, so it will start becoming effective 1/1/10.

MR. WEINHEIMER: Okay, I mentioned two of the three special provisions for GINA that vary from the general HIPAA structure, the exception for very small plans of fewer than two employees, which basically affects retiree plans and special enforcement authority for the Department of Labor.

Then under the authority for Centers for Medicare and Medicaid Services, the HIPAA laws generally apply to state and local governments, but there is also a provision -- this may be because of unfunded mandates or some other reason, I'm not sure what the basis for it was -- but state and local governmental plans generally can opt out of any of the HIPAA requirements if they wish to.

I don't know if you want to go into detail about that, Jim, or if you want me to just go ahead and talk about it.

MR. MAYHEW: Good morning. What Russ is talking about, there is a group of plans called "non-federal governmental plans," and these are essentially plans for

state and local governments, local counties, municipalities, sheriffs offices. There are thousands of these plans that are just throughout the United States.

When HIPAA was enacted in '96, Congress dictated that these plans could affirmatively opt out of the major HIPAA provisions, and they do that by filing a notice with CMS on an annual basis, and then they have to notify their enrollees annually that they continue to opt out.

These major HIPAA provisions that they can opt out of are the nondiscrimination, the special enrollment provisions, the pre-existing condition exclusions. If they opt out, they don't have to follow these rules.

In order to opt out, they have to be self-funded. If they buy insurance for their health coverage, they can't opt out because the insurance carrier has to follow HIPAA, but fortunately GINA created an exception to this. So under GINA, all non-federal governmental plans have to comply with GINA. They do not have the opt-out option.

That is an exception created by GINA to the opt-out provision. So GINA, all non-federal governmental plans, whether they are insured or self-funded, have to comply with the GINA provisions.

MR. WEINHEIMER: Thanks, Jim. So now we're going to dive into a bit more detail [about] the three substantive rules that we have already mentioned. The first one is that the plans and insurance companies -- we say plans, too, and maybe this is being overly technical but you can have a situation where a plan actually covers the employees for more than one employer and they could charge a different rate to different employers.

So it technically applies to both plans and insurance companies, but there is a requirement that plans and insurance companies and HMOs can't charge a higher rate to a group, based on genetic information of anyone in the group. As we said, HIPAA rules already prevent that on an individual basis; now it's prevented on a group basis.

The statute provides an exception or a clarification, that if somebody has been diagnosed, if a disease or a disorder is manifested with respect to an individual, then they can rate them up based on the manifestation of the disease, but they can't based on just having the genetic variation that increases their susceptibility or their likelihood of developing the disease.

In the regulations that we issued, we wanted to make clear -- they just came out yesterday -- that even though the plan can rate up, based on the manifestation of a disease, or an issuer can for the group -- they can't do it, still, on an individual basis -- but they can rate up a group on the manifestation of the disease. They can't rate up additionally based on the greater likelihood of family members of that individual developing the disease.

So let's say we have a family-owned business, and you have adult children that are involved in the business, and one of the parents has Huntington's disease. Either there is a greater likelihood that the children will have it, or maybe we even have knowledge that some of the children have markers for developing Huntington's disease.

So the insurance company can rate up for the one parent that has Huntington's disease that has been diagnosed with it, but they can't rate up additionally for the children that are almost assured to develop Huntington's at some point during their life. They can't rate that up, even though it's a virtual surety. They can only rate up for the one individual with respect to whom the disease is manifested.

That's about all I am going to say about the group rates. I am going to turn it over to Amy to talk about the second rule.

MS. TURNER: The second rule is that plans and issuers can't request or require that an individual undergo a genetic test, and there are three exceptions to that. All three exceptions are statutory exceptions. What we did in the regulations is just provide some examples on how that works and some additional clarifications.

So the first exception is for a healthcare professional who is providing healthcare services to an individual. That person can request that an individual undergo a genetic test. Here is the example. Kaiser Permanente, an HMO, is subject to the rules. They are an issuer.

So if I'm an employee who works for Russ's widget company and Russ buys an HMO contract from Kaiser, I go to my doctor. My doctor might say to me, hey, Amy, I'm looking at your medical history and your mom has a history of breast cancer. You're getting up there in age; I would suggest that you go get a genetic test to see if you are predisposed to getting breast cancer.

My doctor just requested that I undergo a genetic test. He's an employee of Kaiser but he is my doctor; he is actually providing healthcare services to me. There is an exception for that to make sure that my Kaiser doctor can request that I do that, in the best interests of my health and all that good stuff.

We have some examples, though, that clarify (1) this exception only applies if the healthcare professional is actually providing services to the individual. That wouldn't include a claims reviewer, somebody who is deciding afterwards, doing some sort of concurrent review, a retrospective review, for the plan to try to figure out whether or not they're going to pay the claim for the plan. It has to be somebody who I actually see and receive healthcare services from. So that is one clarification.

Another clarification that we made is that the exception is not limited to physicians. It could be someone other than a physician, a physician's assistant, an RN. There could be some other healthcare professional that may suggest that I go for a genetic test, who also may be a Kaiser employee. We clarified that that exception is not limited to physicians. So that's the first exception from

the general prohibition against plans or issuers requesting or requiring that an individual undergo a genetic test.

The second is that plans and issuers can obtain and use the results of a genetic test to make a determination regarding payment of a claim, but we clarify that that is limited. They can only ask for the minimum amount necessary to pay the claim. Here is an example.

I think we have an example in the reg where an individual wants to get a test -- I think it would indicate whether or not they're likely to get celiac disease -- and the person submits a claim to their plan or their insurance company and wants to get it paid.

The plan may seek some sort of verification that the test was performed if they're going to be asked to pay for it, but they can't ask for the results of the test. That would go beyond asking for just the minimum amount necessary.

So if they want some sort of statement from a lab that says, yes, we did perform this test before they'll pay the claim, that's fine, but they can't say, and by the way, can I have the results of that test. That would go beyond the minimum amount necessary.

Also, we clarify that there may be certain circumstances where it would be medically appropriate. I think probably any plan says, we only pay for items and services that are medically appropriate.

So if I just walk into my plan and say, I decided I want this battery of tests because I'm feeling, today, a little under the weather, it doesn't mean that the plan is going to pay for it. They only pay for things that are medically appropriate.

Sometimes it may be that if a plan is going to pay a claim, they might need to request that an individual undergo a genetic test in order to make sure that it is medically appropriate to pay some other claim. If your head is swirling, like, what are you talking about, here is the example that we have in the reg.

We worked closely with NIH. I don't see any of those people here, but I'm sure we worked closely with them. NIH told us that sometimes individuals, after they've had breast cancer, after it's gone into remission, may be put on Tamoxifen, just to try to prevent the reoccurrence. There are some studies that have shown that Tamoxifen may not be helpful in up to 7 percent of breast

cancer patients if they have a variation of the CYP2D6 gene.

So a plan may say, look, we are willing to pay for your Tamoxifen, but first I want you to undergo this genetic test and show me that you don't fall in that 7 percent, because if you fall in that 7 percent and this isn't going to help you at all, then I'm not going to pay for the Tamoxifen. It's up to you, if you want to submit claims to me for the Tamoxifen, you need to undergo the genetic test to show me that it is medically appropriate for you to take Tamoxifen. If that is what the tests bear out, then we will pay for it, but if the tests bear out that it is not likely to help you, then we are not going to pay for it.

So the plan can't require it, but they certainly can request it, and they can make contingent payment of the claims based on an individual undergoing that test and showing that, yes, I don't fall into that 7 percent, and therefore it would be medically appropriate for me to take Tamoxifen.

So that is another example that we have in the reg to illustrate an exception where plans may request that

individuals undergo a genetic test if they want a claim paid.

The third statutory exception that we provide some additional clarification on in the regulation is the research exception. This is a statutory exception. My understanding of the legislative history is, it was something that was added kind of late. I think it was something Kaiser was doing in northern California, where they were essentially doing some genetic research and they had this pool of people sitting there, all these Kaiser members, and they wanted to just ask them, do you want to participate in this genetic research.

Because Kaiser is an issuer, Kaiser can't ask individuals to undergo a genetic test, so an exception was added in the legislation. We provide some additional clarifications on that exception in the regulation that essentially describes when that genetic exception can be claimed.

I'm not sure we provided a ton of additional guidance. We repeat the statutory criteria, which is that the research has to comply with 45 CFR; Part 46, and any other applicable state or local laws that are for the

protection of human subjects. Those include informed consent requirements. There are also disclosures that need to be made to make sure that people who are being asked to undergo this genetic test understand that it is completely voluntary and that any information gathered won't be used to discriminate against them.

The plan or issuer actually can't discriminate against them. They can't take that information and then use it for underwriting purposes. Also, if a plan or issuer wants to claim this exception, they are supposed to file with the government, and we have a form available on the Labor Department's website that is the form that someone would use to file before they could claim the research exception.

So those are the three exceptions to the general prohibition against the plan or issuer requesting or requiring that an individual undergo a genetic test. If there are no questions now, I'm going to send it back to Russ.

MR. WEINHEIMER: Thanks, Amy. Unlike Amy, I haven't been participating in these meetings for a dozen years. Looking at the agenda, we're supposed to go until

9:30, and I know Christina and Jim still want to talk.

Do we have five or 10 extra minutes? If not, then I'll just try to rush through what I have.

DR. TEUTSCH: Take a couple-three more, and then we'll move on. We have some time for discussion at the end, so we have some flexibility.

MR. WEINHEIMER: Okay. Under the third market requirement is that a plan and an issuer cannot request, require, or purchase genetic information from an individual for underwriting purposes, or prior to or in connection with enrollment.

I think the things to be aware of there are, "underwriting purposes" in the insurance market generally is fairly narrow, and it just means we're going to rate someone up or maybe refuse somebody coverage because of their health risks.

In GINA, it is a much broader definition of "underwriting purposes," and if you change their benefits, if you try to give them any kind of incentives, if you lower their co-pays, if you raise their co-pays, if you change the benefits that are available to them, say, as part of a disease management program not based on genetic

information but based on their responding to a request for genetic information, then that would implicate the underwriting purposes, and it would be a violation of the rules to request or require someone to provide that genetic information in order to get a greater benefit under the plan, not only just to get a higher contribution rate or to be denied coverage overall.

The other rule is that you can't request or require genetic information, or purchase it -- we end up using the term "collect" as a summary for request, require, or purchase -- collect information prior to or in connection with enrollment.

The timing of that may be important in some instances because people will sometimes have to re-enroll in a plan every year, so if a plan does collect genetic information but is not using it for underwriting purposes, it's not going to affect your benefits, it's not going to affect the amount that you're charged, but they just want to do that; are you a good candidate for our disease management program, for example.

Then what they can do in that instance is, they can advertise, we have this disease management program.

You can enroll if you want to, but they can't start enrolling, they can't offer the person additional benefits for enrolling. All they can do is say, we have this disease management program.

Getting back to the collection requirement, if they are doing that after someone has already enrolled in the plan and then they're saying, okay, we are going to request some genetic information. You don't have to provide it, it's totally voluntary, but if you respond to our request, we may find out that you're eligible for some of these disease management programs or additional benefits that we do have.

If they provide it, then we said that you determine whether someone is requesting or requiring genetic information prior to enrollment at the time that they are collecting it. This time they are doing it after somebody has enrolled and it is not going to affect their enrollment status.

The fact that they may change plans, they may switch options in one plan and then get back to that option later so it ends up being, in a strict time sense, prior to the time that they later re-enroll in that benefit, doesn't

mean that it was genetic information collected prior to or in connection with the enrollment.

I can see baffled looks on people's faces, but go ahead, ask a question and maybe I can clarify it.

DR. BILLINGS: So I have a health and wellness program at my employer's -- this is hypothetical -- and that health and wellness program is more effective in people with a risk for some disorder, and that risk might be my medical history or might be some aspect of my family history.

Can the employer make, or the health insurance company, make a determination of my risk based in part on my family history, and can they offer any incentives for me to participate in that health and wellness program?

MR. WEINHEIMER: Okay. They can't offer incentives for someone to participate. Let's say that they have a diabetes disease management program and they can't offer incentives. They can give you greater benefits. They can reduce your co-pays, they can reduce your co-pays for diabetes-related claims. They can give you those kind of incentives to join it.

What they cannot do is scour the plan and find

out, do we have any people that are at greater risk for diabetes. We can't start asking people, do you have diabetes, does a family member. They can ask if you have diabetes as an individual, have you been diagnosed with a condition, because that is not genetic information.

The definition of genetic information includes not only the results of genetic tests but the results of genetic tests of family members and medical conditions of family members.

So they can't start asking about family members having the disease. They can't ask about the results of genetic tests for family members.

I can see Amy leaning up to the mic. If you have a clarification, feel free to add it.

MS. TURNER: Well, here's the thing. I see your look of consternation and I feel like you're troubled.

DR. BILLINGS: To put it mildly.

MS. TURNER: I think maybe I can try to provide a little bird's eye perspective. You still might be troubled, but I'll try to give you a little perspective of what we dealt with when working on these regs.

One is that HIPAA already prohibited individuals

from being discriminated against. The discrimination provisions were already in HIPAA. I know that when I came to these SACGHS meetings before -- and am I the only person that calls it SACGHS? -- when I came to the SACGHS meetings before GINA was passed and I listened to the debate about whether or not GINA was needed, one of the things that was debated and talked about was there weren't necessarily a lot of actual cases of discrimination in health insurance in the group market that people were able to find, but there was this fear that people would be discriminated against.

They wanted to keep their genetic information private, and people felt like if they knew that it was private and they wouldn't be asked for it, and they could keep it private, they were more likely to go get genetic tests, get them with their doctor under their real names. So it could be coordinated, and good things would happen.

So what Congress did in GINA, in the group market, is, it really didn't write a nondiscrimination rule so much. There is a small piece Russ talked about, about how the whole larger group can't be rated up by the insurance company, but it had these prophylactic rules to

say plans and issuers can't even ask for this stuff.

Doctors can get it, all sorts of other people can get it. There are all sorts of reasons why people need it, but people are afraid of their employers and their insurance companies having it, because they don't trust that their employers and their insurance companies aren't going to use it to discriminate against them.

There already was a nondiscrimination rule. GINA adds this prophylactic rule and, to be honest, sometimes it's hard to prove why you were fired or why your insurance rate went up. It can be hard to prove, but putting that aside, and I see you're really unhappy, Congress added these prophylactic rules to say plans and issuers can't request it, they can't require it, they can't collect it, they can't purchase it. All these words were thrown out to say they shouldn't even touch it.

There was a wellness exception that was debated in the legislative history and exists in the Title II provisions which are the employment provisions, but in Title I it didn't make it into the final legislation. So we don't have a wellness exception.

So what you have is, if it's a healthcare

professional, again, going to my Kaiser example earlier, if they actually hire a doctor who is providing services, there can be discussions about genetic information and genetic tests.

If the idea is that they're just going to send out a piece of paper and say, tell me your whole family medical history, while that may be used by some plans to do good things, like run it through the computer system and figure out what they might be at risk for and say, hey, you don't even realize that I know your parents are living but they both had heart attacks before age 50 and that puts you at risk, and you might not even know it, go talk to a cardiologist.

I understand they may use it to do good things, but they also may use it to do bad things, and that was the fear, and [that is why] that wellness exception didn't end up in the final legislation.

So where we're at, and I'll turn it back to Russ to go over some of the details, what we tried to do is, essentially say there are ways that plans can still ask for this information, but we are sort of walking a fine line.

They are going to have to be careful and they are

probably going to have to make some changes to how they do it, because the statute says what the statute says. To be honest, although I would like to say that we did all these great things and had all these great ideas on how to handle it, the statute is self-implementing on this point, and I don't think that we really used any regulatory discretion at all. If we hadn't published the regulations yesterday, I think that is what this statute says.

So I think what we really tried to do was issue some examples that would help plans that were trying to do good things to say, you can still do good things if you make some modifications and set it up this way, like Russ is going to talk about. But there is this prohibition that says, you can't just hand people a piece of paper and say, we want all your family medical history and if you don't fill it out, your premium is going to be 50 bucks higher; if you do fill it out, your premium is 50 bucks lower.

Even if the plan is going to use it for the "good purpose," we have this prophylactic rule, and you have these people saying, so I have to turn over my family medical history or my premium goes up 50 bucks a month? I thought this is what I didn't have to worry about anymore

after GINA.

MR. WEINHEIMER: Well, I'm going to try to do this quickly, but there is a fine line that we have drawn, and the sequence is the plan can't ask for genetic information, including family medical history, if it's conditioning any benefit or if it's paying you to provide the information, it can't do that.

It can ask for genetic information, it can just say, if there's nothing connected to it. It can say, we can ask for genetic information.

So they could have a separate medical questionnaire that they send out to people, apart from one that they may provide some incentives for, that says, this is our genetic information questionnaire. You don't have to complete this one if you don't want to, but if you want to, feel free to complete it, and it may help you understand. We may be able to identify certain benefits under the plan that are better for you if you do complete it, but we aren't going to pay you for it. You don't get any greater benefits for completing it. All it is is additional information for us.

Then once they have done that, they can ask for

that information. Then if they get that information, the plan can advertise what programs it has to them without telling them that they need to enroll or something like that. They can just advertise what programs they have, what benefits they have that may be beneficial for that individual, based on the family medical history and genetic information that they provided to them, and if the individual then seeks to enroll, they can provide enhanced benefits within those programs.

They can have enhanced benefits if someone enrolls in a diabetes disease management program, but they can't send out a medical questionnaire saying, listen, we'll give you additional benefits for diabetes if you complete this genetic information questionnaire. They cannot do that. So it's a fine line that we're drawing.

We also have some exceptions for some incidental collection under the statute and that is, basically, if a plan is seeking information from someone, let's say they just, on an annual basis, say, we want you to verify that this is your home address still and these are the people that are enrolled in the plan.

If that's all they are doing, and somebody

provided genetic information and somebody said, oh, well, my dad just died of colorectal cancer and I'm sorry, it took me awhile to get back to it. I know I'm late. I didn't meet your deadline for verifying this, but that was why, well, that would be family medical history that the father had colorectal cancer, but that would be subject to the incidental collection exception.

Well, they weren't asking for it, just asking for a verification of who's in the plan and what your address is. It's just unreasonable to expect that they would provide genetic information there.

If they are sending out a general medical questionnaire and it only applies to the individual, they just say answer this for yourself but they say, is there any other additional information, at the end of the questionnaire, that you would like us to know, well, it is reasonable that someone might start talking about their family history there.

So we've said, if you have general questions that solicit [information], well, a reasonable person might answer by giving genetic information, that's not going to be subject to the incidental collection exception, unless

you specifically say, do not provide any information related to family members and do not provide any information relating to the results of genetic tests.

I think that's pretty much it. So we'll turn the time over to Jim for the individual market.

DR. BILLINGS: Can I just ask one follow-up question on this issue?

My concern is that the healthcare system be able to identify people at high risk for things, particularly when you can do something to prevent the later development of disease, and the burdens of that, and the costs of that, and can we spend the money on something better than that.

MS. TURNER: I think the healthcare system can, if you're talking about healthcare professionals. When you're talking about the payers, there are some limits.

I think, as Russ described, plans can ask for that information if they don't provide an incentive and if they do want to provide an incentive for people turning over their family medical history. They have to do it a certain way, like he described with the disease management program.

DR. BILLINGS: So is genetic information or

family history information being treated as a special class of that kind of information for this particular kind of thing?

MR. WEINHEIMER: Yes.

MS. TURNER: Yes.

DR. BILLINGS: Thank you.

DR. TEUTSCH: Sam?

DR. NUSSBAUM: Sam Nussbaum from Wellpoint. So this is something that is very significant to health insurers and employers, because then I wonder if you've thought this through. I imagine you have seen the various consequences, to build on Paul's statement.

Today, literally millions of people fill out what are termed "health risk assessments," and as you know, this is a well-evolved science in terms of, what are the intended consequences of filling out that health risk assessment. In part, it is to help people be far better informed about risks for them, their potential chronic illnesses and how they can engage in health improvement and avert some of the long-term consequences.

Now, it has also been part of the practice of, as you say, creating incentives to get people to fill out

health risk assessments, because when people fill them out they can become much more involved in these programs and others, and we all wish we had a perfect healthcare system where all of us got recommended care 100 percent of the time, but we don't; we only get it about half of the time.

So the question that I have is, as you've thought through these regulations, that you're dealing with changes for millions of people, and many of the unintended consequences could be far less knowledge, involvement, and preventive activities related to chronic illness.

Certainly, we understand what the intent of GINA was, and the intent of this regulation, but have you actually looked through how many employers encourage and in fact provide incentives for filling out these health risk assessments, and what the long-term consequences might be?

MS. TURNER: I guess I would say -- and Russ, feel free to jump in -- this was the number one issue, health risk assessment, that we heard about in the comment letters that we got in response to the RFI.

Also, this regulation, like every regulation that the government does, has an economic analysis where we discuss the costs and benefits attributable to the statute,

and attributable to exercises of regulatory discretion.

As far as unintended consequences, I'm not sure I can answer that question, because I go back to what is an unintended consequence of all the members in Congress who voted for this overwhelmingly or not. I don't know. There was an exception for wellness programs in Title I, in versions of the bill as they moved through, and it was taken out.

Whether it was an unintended consequence or an intentional decision, I don't know. It all goes back to what Russ was saying, a plan is not allowed to request genetic information for underwriting purposes. There is a statutory definition of "underwriting purposes" that is probably broader than you and the insurance industry would have thought "underwriting purposes" meant.

To be honest, we probably would have interpreted it differently if there wasn't a statutory definition. The statutory definition says that any change in eligibility, benefits, or premiums is an underwriting purpose. So as soon as you're giving people incentives, cash, return on premiums, any sort of penalty if they don't comply, it's an underwriting purpose.

So if you're affecting eligibility, benefits, or premiums based on whether or not they fill out that health risk assessment and turn over the family medical history, there is no statutory authority for us to have come out any other place, to be honest.

I think what we tried to do in the regulations was recognize this point, which we heard loud and clear in the comment letters, and say you can have two separate HRAs. You can have the first one and you get 50 bucks if you fill out that one. Then there is the second one, which is right behind it, and we explain all the same good reasons for filling it out, but whether you fill that out or not, you don't get 50 bucks.

A lot of people might very well fill them both out. When people use the word "incentive," I feel like I always smile a little bit inside, because one person's incentive if they participate is another person's penalty if they don't. That is how we viewed it in wellness programs, going back to HIPAA in 1996.

If I get 50 bucks and you don't, that is a $50 incentive to me but it is a $50 penalty from your perspective. What GINA very clearly says is, you can't

vary individuals' eligibility, benefits, or premiums based on whether or not they respond to a request for genetic information.

We had some ideas for how you might be able to make it part of a disease management program and still offer incentives, but there are some statutory limitations there. I think we tried to do the best we could to preserve what I referred to before as the good things that we recognized that insurers and plans are doing, and just tried to draw this line.

When you talk about a health risk assessment from Wellpoint, I know what you're talking about, but there could be fly-by-night insurance companies sitting in some chair over there that also have their health risk assessment, which looks very different from yours, and there is no way under the statute to distinguish the two.

So I think, again, we tried to use the idea of, just separate your health risk assessment into two: one has a reward; one doesn't. Rely on your healthcare professionals, use the disease management program, and try to keep doing the good things that you are doing without running afoul of the statute that says what it says. It is

sort of this fine line we tried to walk.

DR. TEUTSCH: Why don't we move on to Jim?

Individual Insurance Market Provisions

James Mayhew, J.D.

MR. MAYHEW: I'm going to talk, very briefly, about the individual market.

As Amy said, the individual market, the individual health insurance market is exactly what is says. It's when the individual goes directly to an insurance company to purchase health coverage for themselves or for themselves or their family.

So GINA was really very groundbreaking in the individual market because, unlike the group market, up to the point when GINA was enacted, there was no protection in the individual market in terms of rating based on health status. So in the individual market, if anybody applies for coverage, the insurance company can have them fill out a health form and get medical information from their provider and it would rate them, rate their premiums based on their health status, and also with the exception of a very limited class of individuals called HIPAA-eligible individuals, there was also no protection against basing

eligibility or pre-existing condition exclusions based on health status.

So GINA is really the first type of this protection for most people in the individual market. What GINA does is say that insurance companies cannot base eligibility, it cannot impose pre-existing condition exclusions, nor can they rate premium based on the genetic information of an individual. They can still do those things based on manifested conditions of an individual, but they cannot do those things based on genetic information.

And so we call these provisions the catch-up provisions for the individual market to sort of get them up to speed or same level of protection as there is in the group market in terms of genetic information.

In terms of the prohibition against requiring genetics test and collection, they're virtually the same as in the group market, so I won't go into those because what Amy and Russ said about the rules against collection and requiring genetic tests also apply in the individual market as does in the group market.

So what we simply did in the regulations was we basically reiterated the three new protections, the

prohibition against imposing pre-existing conditions exclusion, basing eligibility and rating premiums based on genetic information, and then in terms of the prohibitions against the testing and the collection, we basically cut and paste what was in the group market, shifted it over to the individual market and just made some just minor changes to make it more relevant to the individual market.

And that's essentially what the individual market regulations do. I just wanted to just talk about one instance about collection. Amy and Russ talked about the health risk assessments in the group market in terms of the wellness programs.

Well, that's not very common in the individual market. What you're going to see more in the individual market in terms of collection is an individual basically applying for individual coverage and they fill out a release to the insurance company for them to get their medical records from their providers and because when they request a medical record from a provider, it can be reasonably expected that there's going to be genetic information in that medical record, what the insurance companies have to do is put a disclaimer in that request

saying please do not send me any genetic information, including family history, and so when the provider gets that, hopefully what they'll do is they'll purge the medical records of any genetic information, any reference to family history or any information on genetic tests or genetic services.

Even if the provider fails to do that and the insurance company receives it, well, as long as they put that disclaimer in there and as long as they don't use that information for underwriting purposes, the insurance companies will be fine because that falls under the incidental collection exception.

If they didn't put that disclaimer in there in the request and they get that information, then they would have violated GINA. So we make that really clear in the regulations and we give the insurance companies specific language they can use for that disclaimer so that they can remember to put the disclaimers in those requests for medical records.

The only other thing I wanted to point out about the individual market is the enforcement. The states are the ones that really have the primary enforcement authority

over insurance companies. States regulate insurance. So each state has a Department of Insurance and so basically in terms of GINA, the states will be the primary enforcement authority, the state Department of Insurance, for the GINA protections in the individual market.

CMS has the authority to step in if a state substantially fails to enforce any HIPAA provision, including GINA. So we've been in the past year and a half, ever since GINA's been enacted, we've been working very closely with the state Departments of Insurance, making sure that they have the state laws so that they can enforce the GINA provisions and we're working with them on an individual basis. We work with them through the National Association of Insurance Commissioners and it seems like at this point most states are on track to get those statutes in order, regulations in order, whatever authority they use to be able to enforce these GINA provisions.

The only other thing I wanted to talk about briefly was the Medicare Supplemental Insurance, also known as MediGap, and these are supplemental coverage that people and fee-for-service Medicare can purchase to help pay the deductibles and co-pays in Part A and Part B and also some

of these MediGap policies cover additional services that Medicare doesn't cover.

Now, I think it's Section 104 of GINA really imposes the same protections as far as people with MediGap policies. It prohibits MediGap insurance companies from discriminating based on genetic information in terms of rating the premium, based on eligibility, or imposing pre-existing condition exclusions, and it has the identical prohibitions against collection and requiring genetic tests.

Now, the MediGap piece is not addressed in these regulations. Instead, the National Association of Insurance Commissioners has what we call a MediGap Model Regulation and it basically incorporates all the federal standards to the MediGap Plan and the states are required to adopt these model regulations in order to be able to regulate MediGap policies in their state. If they don't do that, then CMS is supposed to step in and regulate the MediGap policies in that particular state.

The NAIC amended their MediGap model on September 24th of 2008 to incorporate the GINA provisions. What they essentially did was they cut and pasted the GINA statute

and they put it right into the MediGap model and so the states were required by July 1st of this year, 2009, to incorporate those GINA provisions and most states have done so and the remaining states are on track to get those into their regulatory structure soon.

So that's basically the high-level overview of the individual market and MediGap, and I'm happy to answer any questions.

DR. TEUTSCH: I'm sure there will be some as we get into the discussion period.

Robinsue and Christina, want to talk about Privacy and Confidentiality?

Privacy and Confidentiality

Robinsue Frohboese, J.E. and Christina Heide, J.D.

MS. FROHBOESE: Thank you, Steve. Good morning, everyone. I'm Robinsue Frohboese, the Principal Deputy of the Office for Civil Rights at HHS, and like Amy, I've had the privilege of serving as an ex-officio on this committee since it was created in 2001, and I well remember the early days because, as luck would have it, we were seated alphabetically and I sat next to Francis Collins who, at that point, had not completed the human genome sequence but

did shortly thereafter and actually yesterday was at the White House receiving a National Medal of Science for his incredible efforts in this area.

I remember Francis speaking very passionately about the need for nondiscrimination legislation for genetics information. And so, I just wanted, at this midpoint in the panel, for us to just step back from the bureaucrats, as Amy has said, and to just recognize the importance of this moment and the fact that back in 2001 this committee took on passage of the Genetic Information Nondiscrimination Act as its number one priority. As a result, the Committee held public hearings, did gather testimony about, both, actual discrimination as well as the chilling effect of the fear of use of genetic information. It really was the concerted effort of this committee that, although it took seven years, resulted in the significance of GINA finally being passed.

I think, in your packages there are the press releases that HHS issued with the publication of our GINA regulations, and there you see in the quote from Secretary Sebelius, who invokes the memory of Senator Ted Kennedy as well as his words, that GINA is the first major civil

rights legislation of this century.

So I'm so pleased that the Office for Civil Rights is part of this effort. Our involvement is that Congress wanted to add the extra protection of ensuring that there are HIPAA privacy protections for genetic information, so it directed us to do two things in amending our HIPAA regulation.

First, to make it clear that protected health information does include genetic information and, second, to ensure that genetic information is not used or disclosed for underwriting purposes, and so for the past year, we have been involved in very intensive coordination with our partners at Treasury, Labor, CMS, and EEOC to ensure consistency in our approach in the suite of regulations and in our definitions.

Our Deputy Director for Health Information Privacy at Civil Rights, Sue McAndrew, regrets that she couldn't be here today, but we're fortunate to have the principal author with us, Christina Heide, as well as I would like to recognize in the audience two other members of our staff, Ileana Peters, who will be sitting in during this meeting, as well as Jennifer Weisman, who came to us

first as a AAAS fellow to work on this regulation and we're very fortunate that now she is a permanent employee with us.

So with that, let me turn it over to Christina to give you the broad overview of the HIPAA provisions.

MS. HEIDE: Thank you, Robinsue, and thank you for the invitation to be here today. We are very pleased that our proposed rule was published just yesterday, along with the other Title I regulations, and our rule deals with a different HIPAA, different piece of HIPAA.

We like to think of our HIPAA as the big HIPAA, but I know DOL might think differently.

MS. TURNER: What am I? Chopped liver?

MS. HEIDE: So when I talk about HIPAA, I talk about Title II of HIPAA which includes privacy provisions and under which the Privacy Rule, the HIPAA Privacy Rule was born, which regulates the uses and disclosures that covered entities, certain healthcare providers and health plans may make with individuals' personal health information, what we call protected health information.

And one thing I do want to note, our rule is just a proposal, so we have a 60-day public comment period that

closes December 7th, and we encourage public comment on all aspects of the proposal. The instructions for submitting comments are in the proposed rule itself upfront and I do want to underscore one thing that Robinsue mentioned which was we coordinated heavily with the other agencies, particularly the other Title I agencies, to ensure that the definitions and other cross-cutting issues were the same and you'll see that the definitions are substantially, if not completely, similar across the Title I regulations and we also, as well, consulted with NIH on the technical aspects.

So we have a small piece of GINA, Section 105 in Title I. Congress recognized a distinct privacy interest in the use of genetic information by health plans, distinct from the nondiscrimination aspects of Title I, and Section 105 requires us to amend the HIPAA Privacy Rule to do two things, as Robinsue briefly mentioned.

One is to clarify that genetic information is indeed health information and thus protected under the rules and, two, to then prohibit certain health plans from using or disclosing that information for under-writing purposes. Our section also includes that broad definition

of underwriting. So the definition of underwriting purposes across the regulations is the same.

Our regulation does not deal with what information can be requested. We deal with uses and disclosures once the health plan has the information.

So just a couple of points. The proposal goes ahead and does those two things. [There are] two things I would like to point out and draw your attention to.

The GINA statute required that we prohibit group health plans, health insurance issuers, including HMOs, and the MediGap issuers, to prohibit those plans from using or disclosing genetic information for underwriting purposes.

However, under the Privacy Rule, we cover a number of other types of health plans, as well, including certain public benefit plans, such as Medicare, state Medicaid agencies, the VA Program, the Military Health Program, long-term care insurers, excluding nursing home fixed indemnity policies, and certain accepted benefits, such as limited scope, vision, and dental plans that are separate from group health plans.

And so our definition of health plan is broader than the plans listed in GINA and under the Privacy Rule

currently, an individual's privacy interests are protected, the individual's information is protected without regard to which type of health plan holds the information, and so pursuant to our general HIPAA authority to regulate the uses and disclosures of health plans, we expand the prohibition on using or disclosing genetic information for underwriting purposes to all health plans covered by the HIPAA Privacy Rule to maintain an individual's uniform protection across all plans that we currently have today in the HIPAA Privacy Rule, and also in recognition that we do not expect that all health plans today use or disclose genetic information for underwriting purposes, and certainly most of the public benefit plans may not do underwriting at all in terms of eligibility and determinations of benefits.

So we certainly welcome public comments on that, but I did want to point out that we do have a broader scope in the Privacy Rule.

The other one item I wanted to note is that under the Privacy Rule, an individual has the right to receive a Notice of Privacy Practices of covered entities, including health plans, and for those health plans that do

underwriting, the proposal would require that the plans amend their Notice of Privacy Practices to explicitly state that even though they may do underwriting, they may not use or disclose an individual's genetic information for those purposes, so that individuals are put on notice or made aware of this important new right that they have and this limitation, this change in privacy practices for the plans.

Other than that, we do on our website have the proposed rule. We have a separate page for genetic information now and we do have the proposed rule, links to the other rules, as well as some press releases and related matters. So we encourage you to visit our site. I believe it's listed in the press release that the agency's put out on these rules.

Thank you.

DR. TEUTSCH: Liz, did you have a question?

DR. MANSFIELD: Liz Mansfield, FDA. Is all genetic information considered medical information, and if it's not, where do you draw the line?

MS. HEIDE: The department has always considered that genetic information is protected health information. We say to the extent it otherwise meets the definition.

So what Congress said was please clarify that it is health information. So now we have an explicit reference to genetic information in our definition of health information. Not all health information, however, is protected by the Privacy Rule. It needs to do two things.

One, it needs to be maintained by HIPAA-covered entity, a health plan, HIPAA-covered healthcare provider, for example, and, two, it needs to be individually identifiable in order to be protected by the rule. So we've clarified that it's health information.

The Preamble also goes on to state that it still must meet the definition of protected health information to fall under our Privacy Rule.

DR. TEUTSCH: Could I ask you a follow-on question to that because this committee is very interested in direct-to-consumer testing, as well, and has been and we've actually had substantial discussions about whether the information that's gathered there is health information. You've made clear what you consider health information.

To what extent are those laboratories, many of

which are CLIA laboratories and subject to the rules that you're just describing?

MS. HEIDE: They would be a healthcare provider, but we don't cover all healthcare providers. By statute, the HIPAA rules only apply to those healthcare providers that conduct certain transactions, financial and administrative transactions electronically.
For example, billing a health plan.

So it could be in some cases that these independent labs that do not, for example, bill health plans for the services that they provide to individuals may not be HIPAA-covered entities, but to the extent that they do, they would be covered healthcare providers and subject to the Privacy Rule and they can use and disclose genetic information for treatment purposes. Obviously GINA does nothing in that area to prohibit providers from using the information for treatment purposes.

But it would be dependent -- it's a two-part test for healthcare providers. One, you need to be a healthcare provider and meet our definition. Two, you need to be doing one of the transactions electronically.

DR. TEUTSCH: Marc.

DR. WILLIAMS: Marc Williams. One of the other issues that this committee has been looking at is the issue of the identifiability of DNA samples, and I assume at the present time that the definition of identifiable health information does not quite go to the level of weighing in on the identification of a DNA specimen.

MS. HEIDE: That's correct. We have not opined to date on to what extent or how much of the genetic sequence, if that's all that's there, is identifiable. Obviously, if there are analyses or other identifiers attached to it, that would be a different story.

I mean, we would certainly, before we would do something like that, need input on what to say from you all and the industry, but to date we have not made a determination.

DR. TEUTSCH: Great. Thank you all. Hopefully you can stay for the rest of the discussion.

Kerry Leibig, you want to carry on, talk about Title II?

Title II - Prohibiting Employment Discrimination on the Basis of Genetic Information

Kerry Leibig, J.D.

[PowerPoint presentation.]

MS. LEIBIG: Okay. Fancy. All right. I went ahead and provided some PowerPoint slides because I have been traveling around talking about Title II, which is the employment discrimination provisions of GINA, to EEOC personnel, to some employers who've asked for sort of a preview of what the Title II regs are going to look like, and I went ahead and just modified it.

Usually this takes about an hour and a half and I modified it, so I'm hoping it's going about 20 minutes. So give a wave, Sarah, Steve, if I'm going over.

Title II becomes effective on November 21st. We are in the home stretch now of issuing our final regulations, but we haven't done so yet. So today, we're going to be talking about our proposed regulations and I will be pointing out topics on which we got a good deal of comment sort of so that you can be aware of where it's likely that the final regulation is going to be a little bit different.

And on this, I think everybody has handouts that parallel the slide show here and you'll see that I've put

in regulatory sites for the various topics, but on my way over here, I realized that I didn't put in the whole site because I'm so used to talking in shorthand. But when these regulations are issued, they will appear at 29 CFR 1635 and on your slides, you'll see reference to 1635 point something or other to point you in the right direction and that's 29 CFR 1635.

Okay. So we're just going to jump right in. Feel free to ask questions as I go along or you can wait until the end, but basically we have three rules under Title II. It prohibits the use of genetic information to make employment decisions, it restricts the acquisition of genetic information by employers and other entities covered by GINA, and it requires that covered entities keep genetic information confidential, subject to limited exceptions.

I can't move because I don't have a microphone attached to me, so I'm feeling a little awkward here, but that's why I'm standing right here.

In any case, in a moment I'll give a definition of genetic information for purposes of GINA, but the important thing to see here when we're talking about the three basic rules is that the first rule, which prohibits

the use of genetic information, is an absolute rule.

Under no circumstances can an employer use genetic information to make an employment decision and this is intended to operate pretty much like Title VII of the Civil Rights Act of 1964's prohibition on using race or sex, for example, to make employment decisions. You can't use genetic information to decide to hire someone, fire someone, promote someone, give someone a raise, make any decisions related to terms, conditions, or benefits of employment, and that includes a prohibition against harassment based on genetic information and an anti-retaliation provision. If someone takes protected action under GINA, they can't be retaliated, for example, for filing a charge of genetic information discrimination. So it's very broad. It's also pretty simple to understand because there are no exceptions.

The second two rules, in particular the second rule, which restricts the acquisition of genetic information, has six exceptions and therein lies the complication and that's where we got most of our comments and I'm going to talk more about that in a moment.

And then the third rule is just a basic

confidentiality rule. Genetic information, like all medical information, must be kept confidential. There's six limited exceptions that are very similar to the exceptions we have under the Americans With Disabilities Act for confidential medical information and we'll talk about that in a moment.

Very briefly, obviously usually I'm giving this talk to EEOC investigators or employers and they have no idea what we're talking about when we say genetic information. Obviously that's not a problem here, but I did want to go ahead and make sure we're all on the same page and know what we're talking about under Title II here on genetic information.

First, obviously an individual's genetic tests, the proposed rule gives a specific definition of this based on the statute and also some examples of things that are genetic tests and some examples of things that are not genetic tests.

This is an area where we got a lot of comments, where people wanted more examples and they wanted the examples to appear in the regulation as well as the Preamble, and you can expect to see some of that in the

final reg, but obviously an example of a genetic test would be a test to determine if someone had the gene that predisposed them to breast cancer. That would be a genetic test, but a drug or alcohol test is not a genetic test. A test for the presence of non-human DNA, RNA, or virus, like an HIV test, is not a genetic test. So we're talking about genetic tests, not other kinds of medical tests.

Genetic information also includes genetic tests of family members and family members is very broadly defined. It includes not only your children, spouse and husband, adopted children, but also all of your relatives up to the fourth degree, so your great-great-grandparents and your first cousins once removed, which means the children of your first cousins, information about them, genetic tests about those family members is also genetic information.

Very importantly, genetic information includes the manifestation of disease or disorder in family members. In other words, your family medical history, and this is important and this is where we're expecting that we're going to get the charges that we get because this is an area where employers do have family medical history. It's

probably not that current right now that employers would get your information about your genetic tests or genetic tests of family members, but family medical history is the kind of information that employers often have.

And finally, genetic information includes the request for or receipt of genetic services by an individual or a family member. That includes genetic tests, genetic counseling, genetic education, and the genetic information of a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology. So that's what we mean when we say you can't use genetic information.

Okay. Did I see a question? Yes?

MS. ASPINALL: I just have a quick question. When you talk about, I think I heard it right, non-human samples, like you used the example of AIDS virus, I'm assuming you mean sort of AIDS virus genotyping where you're --

MS. LEIBIG: HIV tests.

MS. ASPINALL: HIV tests. Where you're getting the information on the virus itself and therefore not considering that human testing. Is that --

MS. LEIBIG: That's right. That's correct. An HIV test and all of these examples where we're talking about genetic information, genetic tests, this is not an area in which EEOC has any expertise or experience. So these all came from experts we consulted at NIH.

MS. ASPINALL: So did you talk at all about information on the tumor in a cancer patient in the same way as you're talking about information on the virus in an AIDS patient? Did you use any examples in looking at the tumor itself as opposed to genetic basis of the individual?

MS. LEIBIG: We certainly don't have anything on that in the proposed rule. The final rule is going to add some examples. What exactly those examples are going to be, I can't say right now. It's still in the process of being discussed, but anything that we did add or any definitions that we clarified from the statute, we did so because of NIH and other experts because EEOC doesn't know anything about that. Does that make sense?

MR. WEINHEIMER: Yes. I would just like to add to what Kerry said. The Title I provisions, we share the same definitions, and we relied on NIH to tell us what constitutes that.

But I'll take a stab at your question when you talk about cancer. I think the tumor is part of the individual -- has the individual's DNA in the tumor. So I don't think that it would be excluded the way that HIV is which is some other organism, if a virus rises to the level of a full organism, but, anyway, I mean, it is separate DNA for the virus, whereas the tumor, I think, would have the individual's DNA.

MS. ASPINALL: That's what I was trying to understand, the subtlety, and then the second question was are all the Title I provisions in terms of definition consistent with Title II?

MR. WEINHEIMER: We have minor differences, but they're mostly consistent, I would say.

MS. LEIBIG: That's right. We did work together and they're mostly consistent. There are a few differences when you're talking about what a family member means in terms of dependent due to some provisions in ERISA, but essentially we did sit down together and try to make sure they're going to be the same.

Okay. So the first rule prohibited use, absolute rule.

The second rule has to do with acquiring genetic information. Covered entities shall not request or require or purchase genetic information of an applicant or an employee and here there are six exceptions and there's sort of six situations where employers are permitted to acquire genetic information and, as you'll see, they sort of take into account the legal framework that already existed as well as just how the employment life works.

So the first one is intended to protect the supervisor who is walking down the hall one day and overhears a subordinate on the telephone saying, oh, I had a terrible weekend, my son was diagnosed with asthma. That is family medical history about that employee because that's a manifestation of a condition in a family member. The employer has now acquired genetic information.

Similarly, if an employer says or a supervisor says, oh, how are you doing today, how was your weekend, and in response, an employee says, oh, it was terrible, my sister was diagnosed with breast cancer, they've just acquired genetic information.

Does that violate Title II? No. The statute and the regulation anticipated this problem and we have our

first exception which is no liability for inadvertent acquisition. This protects covered entities that unwittingly receive otherwise prohibited genetic information. You'll see some examples there. The unsolicited e-mail message, the how are you, or documentation to support a request for reasonable accommodation or other lawful request for health information that employers do under various laws or policies.

Now, this is an area that we got quite a bit of comments on, mostly having to do with situations where employers are lawfully requesting medical information, and we had some civil rights groups who were saying, look, any time an employer's requesting medical information, be it in response to reasonable accommodation requests or fitness for duty, post-offer exam, they should know that they're probably going to get genetic information.

It's reasonably likely they're going to get that information and they shouldn't be able to take advantage of the inadvertent exception, and then we had employers who were concerned that their HR departments were going to be responsible for telling doctors who were doing these exams

for them how to do the exam and they wanted the rule to say no matter what, employers can't get the information but doctors can collect it.

So this is an issue that we're going to be -- you should expect some changes in the final regulation. We're going to be fine-tuning it, but the general rule still exists that it is a violation of GINA for an employer to request, require, or purchase genetic information.

It's interesting because, I don't know how many of you know this, but under the Americans With Disabilities Act, which EEOC also enforces, employers may conduct post-offer medical exams and inquiries or fitness for duty exams, as long as they meet the ADA requirements, and for example, under the ADA, once you make a job offer to an employee, you can condition it on a medical exam and that medical exam can include any kind of medical inquiries that you'd like, any kind of exam, as long as you treat everyone entering for that same position in the same way.

And as you can imagine, most of these post-offer exams, as well as fitness for duty exams, which are what we call the exams that an employer sends a current employee to under certain defined circumstances, but these exams

usually involve questions about family medical history. All right.

Under GINA, as of November 21st, 2009, an employer that asks for genetic information as part of an inquiry or medical exam will not be considered to have acquired the information inadvertently. That's obvious. If you ask for it, it's not inadvertent when you've receive it.

So GINA changes the landscape here. Under the ADA, this kind of questioning was okay in a post-offer fitness for duty exam. It no longer is okay under GINA. Covered entities are prohibited from obtaining genetic information through any type of exam required of employees.

Again, we got a lot of comments about this. We are definitely going to have some more examples in the final regulation trying to clarify how this is going to work, but just keep in mind there's no exception for an employer doing a post-offer exam to obtain family medical history or any other kind of genetic information.

Okay. What about employer-sponsored health services and here where we get into the issue of wellness programs. As Amy said, although Title I does not have an

exception for wellness programs, Title II's exception for employers obtaining genetic information through wellness programs did survive. It is in the statute.

An employer may request genetic information as part of health or genetic services, such as a wellness program, as long as specific requirements are met and this is what was said in the proposed rule. The wellness program must be voluntary. That means the employer must not require participation nor penalize employees who refuse to participate. You have to have a written request, knowing authorization. The information goes only to the healthcare provider and the individual with the employer getting the information in the aggregate.

In the proposed rule, we specifically asked for comments on the scope of the term "voluntary," and we got a lot of comments and these comments ranged from groups that were of the opinion that in order to be considered voluntary, a voluntary wellness program and therefore a wellness program that was permitted to collect genetic information, there should be no financial inducements.

So we got a number of comments that suggested that approach, and we got a number of comments on sort of

the other side of the line there that wanted us to adopt the HIPAA 20 percent rule, meaning as long as any inducement was limited to 20 percent of the cost of group or individual health insurance, then it would be considered voluntary.

This is an area in the final regulation. We will go through the comments we have received. We'll discuss them, and we will have an answer, but we don't have one yet because the final regulation isn't out there yet.

Questions on that? I think probably some of you in the audience are people who submitted comments on this proposal and you will see that we'll address those in the final reg.

Okay. Number 3, I'm going to certainly do a little more quickly here because these are pretty obvious exceptions.

Under the FMLA and other similar state and local laws, individuals requesting leave often have to provide family medical history because, if they're asking for leave to care for a seriously ill relative, they have to describe the relative and the illness. That's not going to be a violation of GINA. Asking an employee to fill out the

general FMLA Certification Form that requires that they give the information about their relative is not a violation. Of course, any information that an employer does get has to be kept confidential, treated as confidential medical record.

Exception Number 4. This was intended to cover the supervisor who's reading the newspaper one day and comes upon an obituary of an employee's father and it says they passed away after a long struggle with lung cancer. They've just acquired genetic information. Really, this is sort of a subset of inadvertent acquisition, but Congress created a separate exception, and it says that it's permissible for an employer to acquire genetic information through commercially and publicly available documents such as newspapers, periodicals, magazines and books, also information obtained through electronic media, such as television, movies, or the Internet. The exception does not apply to medical databases, court records, or research databases available to scientists on a restricted basis.

This exception is another area where we got a lot of comments having to do with, what about Facebook, what

about the websites, blogs, all these sorts of 21st century media sources. Again, you're going to see when the regulation comes out at 1635.8(b)(4), there is going to be a lot more detail of how Title II works in relation to those kinds of sources.

We had, again, the range of comments from civil rights groups who were very concerned that an employer who was searching for the information, purposely looking for genetic information but happened to find it in the newspaper, wouldn't be able to take advantage of this provision because, really, it's supposed to be the type of inadvertent acquisition, not the employer who is trying to get this information.

Then we also had employers who were very concerned because they use the Internet as a tool when they are doing the application process. They do Google searches. They want to look at people's Facebooks to determine if they are going to be someone they want to hire. So we had a broad range of comments, and we will be addressing them.

The fifth exception. It's permissible to acquire genetic information through genetic monitoring. Again,

that monitoring has to meet specific requirements and this is dealing with employers that, either because they have to under OSHA or Mine and Safety Health Administration rules, they have to monitor the biological effects of toxins in the workplace or employers who are voluntarily monitoring the effect of some toxin that their employees are exposed to, and GINA has carved out an exception, saying yes, this is okay again, as long as you notify your employees, they give knowing authorization, they voluntarily comply with the genetic monitoring.

Of course, if the genetic monitoring is required by law, you don't have to make it voluntary, and again the information is protected. It only goes to the employee and the healthcare provider, the covered entity getting the information in the aggregate.

And the last exception is very limited. It only applies to employers that engage in DNA testing for law enforcement purposes as a forensic lab or for purposes of human remains identification. These employers may require genetic information from employees to the extent that genetic information is used for analysis of DNA markers for quality control to detect sample contamination.

We didn't really get any comments on this. We did get some sort of informal comments from people who say this kind of DNA marker isn't even genetic information, but we are not experts on that and this is an exception that's in the statute, so obviously we're putting it in the regulation and this is an exception to the general rule against acquisition.

So to sum up all of that, I just want everyone to keep in mind that the rule is employers cannot acquire genetic information. They are not permitted to acquire it.

There are six circumstances in which they're allowed to get the genetic information, despite the general rule. If they get it outside of those six exceptions, it's a violation of GINA in and of itself, even if they don't use it. Okay? This works very much like some rules under the Americans With Disabilities Act that says you're not allowed to ask certain questions, certain disability-related questions, we call them, even if you don't use the information. You're not allowed to have it in itself. Acquiring it is a violation.

The third basic rule, again beginning November 21st and thereafter, genetic information that an employer

has must be kept confidential and must be placed in a separate medical file. ADA file is okay. It means that this has been a rule about medical information under the ADA and before that under the Rehabilitation Act for years. You can keep your genetic information in the same file that you keep your ADA information, but it must be kept separate from personnel records.

There are six disclosure rules. They're going to be listed at 29 CFR 1635.9(b). I don't have time to get into them, but they're things like you can disclose genetic information to government officials who are investigating compliance with GINA. You can disclose genetic information in response to a court order that specifically asks for genetic information, and there are four other rules that I won't get into.

There's a specific section of Title II that addresses the relationship between Title I and Title II and we call it The Firewall. In the proposed rule, we basically say this is -- the basic point of this rule is to prevent double liability. It's to ensure that a health plan or insurer provisions or actions are addressed and remedied through ERISA, Public Health Service Act, Internal

Revenue Code, while actions taken by employers and Title II-covered entities are remedied through GINA Title II.

The example we give is an employer who fires an employee because they get some genetic information and they anticipate that this will increase the person's health claims in the future, so they fire them. That's an employment action. The fact that it involves health benefits does not remove it from Title II liability because health benefits are a term, condition, or privilege of employment, and taking an action based on genetic information that's an adverse action having to do with terms, benefits, or conditions of employment violates Title II.

At the same time, health plan or issuer provisions or actions that have to do with decisions about pre-existing condition exclusions or health premiums, those types of decisions made by health plans are subject exclusively to Title I and The Firewall is an attempt to make that clear.

Now most of the comments we got about our Firewall discussion were we need more examples. We don't understand how this is going to work. We need more real-

life examples, and the final regulation is going to have more examples and hopefully clarify some of the questions that were raised in the comments.

And that's it. So feel free to ask questions. Okay. Yes?

DR. WILLIAMS: Marc Williams. So just to make sure that I understand the statute and the one exception. So if we imagine a situation where we have information that a specific genetic variant would increase the risk of an adverse health outcome in an individual that's exposed to something in a workplace environment, in other words, a toxin or something of that nature that they would reasonably be expected to come in contact with if they had a specific job, the employer could not use that information on the front end, either in a hiring decision or in a decision about where within the company that individual could work, but they would be able under a monitoring program to be aware -- well, in the sense that whoever they have designated to do the monitoring, i.e., the healthcare professional, would be able to access that information and do health monitoring for toxin outcomes related to that.

Is that a --

MS. LEIBIG: Right.

DR. WILLIAMS: -- fair interpretation?

MS. LEIBIG: Yes, because you can't use genetic information to make an employment decision, even if your intent is to protect someone. You certainly want to -- first of all, if it's required by law, OSHA or something, you're going to be doing your monitoring program that's allowed.

The only example that ever came up of a totally voluntary genetic monitoring system, there's only one, I actually can't remember what the toxin was, but most of the employers who are doing this are doing this because they're required to do so by OSHA.

So the way Title II works is that, yes, obviously you could still do this. You get the person's authorization and you obviously -- if they end up being someone who is likely to be harmed by this, the healthcare provider would explain that to them, but it has to be voluntary and so if you, in response to the monitoring that you did, fired them or made them take a different job, that would make it involuntary and that violates GINA because we say you can't use the genetic information, even in the

situations when you're allowed to acquire it.

So hopefully the person, if they were educated properly, that, look, you're going to die or you're going to get some terrible disease if you continue in this position, they will voluntarily choose to not operate in that position.

DR. TEUTSCH: So following up on that question, so what happens if a person presumably has that information, decides to keep the job, the employer obviously does not know about this particular enhanced risk because of the genotype? Does the employee then -- if the employee suffers harm subsequently, can they come back at the employer or is the employer protected?

MS. LEIBIG: Well, we don't address that in the proposed rule. There was a comment that raised this issue and the problem is if an employer takes action -- I'm speaking as myself here. I don't know what the final -- I can't say what the final regulation is going to say, if it's going to address that, but when you think about how GINA works and what the acquisition exception is, if an employer took action against the employee, they would be retaliating against them --

DR. TEUTSCH: Right.

MS. LEIBIG: -- or else using genetic information and they're not allowed to do that.

GINA doesn't speak to -- I assume you're talking about an employee who then sues the employer for wrongful death or some --

DR. TEUTSCH: Right. Presumably they've accepted this because they've been informed of it, right?

MS. LEIBIG: You know, GINA doesn't speak to that. So I imagine there could be a situation when an employer is faced with this situation -- although, of course, remember the employer doesn't have specifically identifiable genetic information. So they're not going to know who has it.

DR. TEUTSCH: They don't know.

MS. LEIBIG: But whatever. That doesn't always work out so well. So let's say there's a situation where the employer gets it.

I suppose they would be in a situation where having to decide do they want to violate GINA or do they want to risk a lawsuit, I don't know what the courts would do with that. One would hope that they would look at the

provisions of GINA and see that this is a requirement that the employer was following, but I can't say whether that's the case or not, and GINA itself doesn't speak to what would happen.

DR. WILLIAMS: So carrying that on one step further, again assuming that an employee then develops a healthcare condition related to an exposure for which they have a predisposition, are there any comments specific to unemployment benefits, disability insurance, or any protections around those types of things from this type of information? Does that make sense?

MS. LEIBIG: I don't --

DR. WILLIAMS: So the individual has a genetic predisposition to develop a health consequence from an exposure at work. They develop the health consequence and they become disabled as a consequence of that. Can the disability insurance say, well, you shouldn't have been doing that, we're not going to be paying your disability?

MS. LEIBIG: I actually don't know. GINA Title II doesn't speak to that and EEOC actually doesn't have any authority over how disability social security works. I don't know of anything in GINA that deals with that.

Perhaps there are already existing social security rules on that that someone else can speak to, but I do not know.

MS. ASPINALL: On the incidental acquisition of information, understanding in the rules you described, is there an obligation by the employer to document that in the separate medical file or once they -- is there anything they have to do, employers have to do or not do with the incidental acquisition?

MS. LEIBIG: Okay. We call it inadvertent acquisition. I think under Title I, it's call incidental.

Obviously any genetic information that an employer receives in writing has to be kept in the confidential medical file. Any genetic information they receive has to be kept confidential, but an employer -- and again this is not something we say specifically in the proposed rule, but we did receive some comments and my sense is that our position is going to be an employer need not reduce information they receive orally into writing. So they need not do it, but there could be a situation where employers want to do it just for their own record, say okay, we're going to have it written down somewhere that this information was received, here's why it was

inadvertent just for the purposes of defense at a later point, but the regulation doesn't require them to do it nor does it make it unlawful to do it. So it's sort of up to individual employers.

DR. TEUTSCH: Julio.

DR. LICINIO: I have a question about the acquisition of the information. So you said that if it's available, it's okay, but let's say you go to a site that's specific to researchers or to medical professionals, then it's not.

But let's say if you just do a general like you do a web search and come across information, that's one, and then also if the information is available on social networking sites, how is that kind of permissible to get that or not?

MS. LEIBIG: Well, in the proposed rule, we didn't address that. We asked for comments about what people thought about the social networking sites, other sort of Internet-based information that is out there, and we got a great number of comments.

We are going to be addressing and explaining the position of Title II in our final regulation, but because

the final regulation isn't issued yet, I can't get into specifics, but I can tell you a lot of people raised a concern about the employer who just wanted to Google applicant A. They Googled them, that's part of their regular employment process, a bunch of websites come up, and they start clicking away. Are there websites they have to avoid? What actions should they take? We will be addressing that in the final regulation.

When it comes out, hopefully prior to November 21st, I'm happy to come back at the next meeting and talk in detail about the decisions that were made, but I'm not allowed to talk about it until then.

DR. LICINIO: Is that also going to cover like if I put some genetic information in my Facebook page --

MS. LEIBIG: Yes.

DR. LICINIO: -- and is that --

MS. LEIBIG: That will be discussed. We discussed -- we're going to be -- we got comments about Facebook, MySpace, LinkedIn, websites, blogs, everything you can imagine, and we will be talking about that and hopefully answering all of those questions.

DR. TEUTSCH: We just have a few minutes, and I

want to make sure we get back to the other panelists, as well.

Are there any other questions you want to direct to any members of the panel? Yes, David.

DR. DALE: Yes, I just have a general question. I think that in many ways in this discussion we're dealing with old versions of what might be regarded as genetic information, that is specific tests or test results, whereas when you begin to link clinical information with likelihoods of genetic disease or poly-genetic disorders, it becomes more complicated.

I just wondered how -- because in this area of discrimination, it's so likely that, although you don't have a specific test, in fact it's genetic information that's the basis for discrimination, I wonder how broadly you reviewed the issue in the public law where it defines genetic information and genetic tests.

MS. LEIBIG: Well, what I can say about EEOC, and I think this is probably the case for all of us, is that none of the Title I or Title II agencies are experts on medicine or genetics or any of that. So we took what the statute said and we brought in experts from NIH and

basically did what they said.

MR. WEINHEIMER: Well, let me come in. It seems to me you aren't asking about family medical history here. You're talking about an individual's own conditions and because of either the way that they manifest certain symptoms that they have, certain collections of conditions that they have, that you can discern from that a genetic condition. Is that what you're --

DR. DALE: Well, I would include family history but also having a genetic phenotype and a clinical phenotype. There are a lot of other things that are involved in determining the genetic aspects of the outcome for illness or health.

MR. WEINHEIMER: Certainly, it's going to be protected under both Titles I and II, to the extent that family medical history is relied on because family medical history is defined as genetic information.

If it's something else with an individual's own medical condition, I don't know. I'm stumped there. I don't know if anybody else has anything else to add.

MS. LEIBIG: Well, if it's a condition, as Russ said, that's manifested, even if there's proof that it's a

genetic basis, let's say you have breast cancer and you took a genetic test and it shows that you have the gene that was likely to lead to breast cancer, once you have the manifested condition, once you have breast cancer, at least in terms of Title II, you're no longer protected by GINA.

If you have a manifested condition, you're protected from employment discrimination because of the Americans With Disabilities Act, if that condition rises to the level of a disability. So even if the manifested condition you have has a genetic component or genetic basis, once it's manifested, Title II is no longer at play.

MR. WEINHEIMER: Well, and similarly, you could say GINA doesn't apply but that's because the HIPAA nondiscrimination requirements already prohibit that kind of discrimination based on a manifested condition. So it's as if there was no need for GINA to take care of the manifested conditions. It's only when they haven't been manifested that GINA had to step in.

DR. TEUTSCH: First, let me thank Robinsue, specifically, for reminding us how important this legislation was and how far we've come and now we're talking about a lot of the refinements of all of this and

so thank you for that and thanks to all of you for all your work in bringing this law to practical reality with all the implementation. It's obviously extremely important and we do appreciate it.